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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,298	11/21/2001	Alan D. Schreiber	555-63	9500

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EXAMINER
ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	11

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/989,298	SCHREIBER ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1,2,11-21 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-10 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 + 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

RMD 6/25/03

Applicant's election with traverse of Group II in Paper No. 9 is acknowledged. The traversal is on the ground(s) that Groups II and III should be rejoined since a thorough search of Group II would likely encompass the subject matter of Group III and hence no undue burden would be placed on the examiner. This is not found persuasive because the searches of the various groups would not be coextensive in scope.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-25 are pending. Claims 1-2, 11-21 and 23-25 have been withdrawn from consideration since they are drawn to non-elected inventions. Claims 3-10 and 22 are currently under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-10 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 14-15 and 17 of U.S. Patent No. 5,776,910 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6).

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding **an** FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10). Finally, the claimed particle can be a bacterium (claim 9), an antibiotic resistant bacteria (claim 22) or a mycobacterium (claim 22).

U.S. Patent No. 5,776,910 recites claims drawn to a method of increasing phagocytosis of lung cells by introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (claims 1 and 7-9). Said Fc receptor can be an FcγRIIA receptor (claims 1, 14-15 and 17). Moreover, said cells may be normally phagocytic, i.e. normally express FcγRIIA, (claims 2-4) or normally non-phagocytic, i.e. normally do not express FcγRIIA (claims 5-6) It should be noted that the U.S. Patent 5,776,910 does not recite that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed in U.S. Patent 5,776,910 read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability (see

Downey et al. page28441-28442). Finally, while methods recited in U.S. Patent 5,776,910 are not explicitly drawn to bacterium, an antibiotic resistant bacteria or a mycobacterium they are encompassed by claim 1 which is interpreted as being drawn to the phagocytosis of any "particle".

Claims 3-10 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 9-11 of U.S. Patent No. 6,068,983 in view of Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 –IDS-6).

U.S. Patent No. 6,068,983 recites claims drawn to a method of increasing phagocytosis of lung cells by introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (claims 1 and 9-11). Moreover, said cells may be normally phagocytic, i.e. normally express Fc receptors, i.e. FcγRIIA, (claims 2-4) or normally non-phagocytic, i.e. normally do not express Fc receptors, i.e. FcγRIIA (claims 5-6, 8). It should be noted that the U.S. Patent 6,068,983 does not recite that the claimed Fc receptor is FcγRIIA or that said receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif) and FcγRIIA is encompassed by the broadly recited genus of Fc receptors. Moreover, while the methods disclosed in U.S. Patent 6,068,983 read only on increasing the phagocytic activity of cells by the introduction of DNA coding for an Fc receptor, said methods induce an increased phagosomal maturation resulting in bactericidal capability (see Downey et

al. page28441-28442). Finally, while methods recited in U.S. Patent 6,068,983 are not explicitly drawn to bacterium, an antibiotic resistant bacteria or a mycobacterium they are encompassed by claim 1 which is interpreted as being drawn to the phagocytosis of any "particle".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Downey et al. (Journal of Biological Chemistry Vol. 274, No. 40, pages 28436-28444, 1999 – IDS-6).

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding **an** FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5) into said cells wherein said cells do not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10). Finally, the claimed particle can be a bacterium (claim 9).

Downey et al. disclose methods for transfecting FcγRIIA into non-myloid cells (see page 28437). Said methods conferring on said cells not only particle internalization (phagocytosis) but also phagosomal maturation and acidification. Said phagolysosomes were further disclosed to limit the growth of internalized microorganisms (see pages 28441-28442). It should be noted that Downey et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif).

Claims 3-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreiber et al. (U.S. Patent No. 5,776,910).

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding **an** FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10).

Schreiber et al. disclose methods of modulating the phagocytic potential of cells that are naturally phagocytic (e.g. macrophages) and methods of rendering cells phagocytic that do not naturally possess that function (see column 4, lines 48-52). Schreiber et al. further disclose that said methods provide innovative treatment regimens that can be used to combat infections (see column 4, lines 52-54). Said methods comprise introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (see column 10 lines

24-27 and column 10, line 63 to column 11, line 1). Moreover, Schreiber et al. disclose that said Fc receptor could be an FcγRIIA receptor (see Example II). It should be noted that Schreiber et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed by Schreiber et al. read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability.

Claims 3-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Schreiber et al. (U.S. Patent No. 6,068,983).

The instant invention is drawn to methods of enhancing the ability of a cell to degrade a particle comprising introducing a nucleic acid encoding **an** FcγRIIA receptor comprising at least one L-T-L peptide sequence in its cytoplasmic domain (claims 3-5). Said cells can normally express FcγRIIA (claims 6 and 8) or not normally express FcγRIIA (claims 7-8). Said nucleic acid can be introduced into said cell via a liposome, a bacterium or a viral vector (claim 10).

Schreiber et al. disclose methods of modulating the phagocytic potential of cells that are naturally phagocytic (e.g. macrophages) and methods of rendering cells phagocytic that do not naturally possess that function (see column 4, lines 48-52). Schreiber et al. further disclose that said methods provide innovative treatment regimens that can be used to combat infections (see

column 4, lines 52-54). Said methods comprise introducing into cells via a viral vector, liposome or a non-infectious bacterium a DNA molecule coding for an Fc receptor (see column 10 lines 24-27 and column 10, line 63 to column 11, line 1). Moreover, Schreiber et al. disclose that said Fc receptor could be an FcγRIIA receptor (see Example II). It should be noted that Schreiber et al. do not explicitly disclose that the claimed Fc receptor comprises an L-T-L sequence. However, said L-T-L sequence (motif) is normally present in the cytoplasmic domain of the FcγRIIA receptor (at the C-terminal of the ITAM motif). Moreover, while the methods disclosed by Schreiber et al. read only on increasing the phagocytic activity of cells by the introduction of DNA coding for FcγRIIA, said methods induce an increased phagosomal maturation resulting in bactericidal capability.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
June 25, 2003